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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,986	09/11/2006	James McCarthy	112701-667	6606
29157	7590	11/05/2009	EXAMINER	
K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690			SWOPE, SHERIDAN	
			ART UNIT	PAPER NUMBER
			1652	
			NOTIFICATION DATE	DELIVERY MODE
			11/05/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

chicago.patents@klgates.com

Office Action Summary	Application No. 10/559,986	Applicant(s) MCCARTHY ET AL.	
	Examiner SHERIDAN SWOPE	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 5-16 and 22-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 17-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' Request for Continued Examination of October 5, 2009, in response to the action of July 6, 2009, is acknowledged. It is acknowledged that no claims have been cancelled, amended, or added. Claims 1-44 are pending. Claims 5-16 and 22-44 were previously withdrawn pursuant to 37 CFR 1.142(b). Claims 1-4 and 17-21 are hereby reexamined.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Utility

Rejection of Claims 1-4 and 17-21 under 35 U.S.C. 101/112 because the claimed invention lacks patentable utility, for the reasons explained in the prior actions, is maintained.

In support of their request that said rejection be withdrawn, Applicants provide the following new argument. The declaration by James McCarthy, filed herewith, shows that the protein of SEQ ID NO: 2 has ~70% homology with the CPR4 protein, a known plant cysteine protease (Fischer et al, 2000; Exhibit B).

This argument is not found to be persuasive for the following reasons.

It is noted that no "Exhibit B" has been filed. Nonetheless, the Examiner has accessed Fischer et al, 2000 from public databases.

It is acknowledged that SEQ ID NO: 2 has ~70% homology with the CPR4 protein discussed by Fischer et al. However, Fischer et al fails to teach that said CPR4 protein has protease activity. Neither Figure 2 nor 3, which demonstrates the protease activity of other proteins, demonstrates protease activity for CPR4. Moreover, Fischer et al states (pg 92, para 2):

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“The amino acid (aa) sequence of an additional papain-like cystein proteinase, called CPR4, was deduced from a cDNA (EMBL accession number Z99172) that had been selected from a cDNA library raised against mRNA of maturing vetch cotyledons (Becker *et al.*, unpublished). ... The aa sequence of CPR4 displays only little similarity to proteinase A (25.4%) or CPR1 (23.6%) but 78% identity to the cDNA-derived amino acid sequence of soybean proteinase GMCP3 (Nong *et al.*, 1995) and 50% identity to CPR2.”

Thus, Fischer et al “cloned” the CPR4 sequence from the EMBL database and provides no experimental evidence that CPR4 has cysteine protease activity. Fischer’s assertion that the CPR4 protein is a cysteine protease is based on homology with the GMCP3 protein of Nong et al, 1995. However, Nong et al also fails to demonstrate that their GMCP3 protein has protease activity. Therefore, Fischer et al fails to provide evidence that the CPR4 protein has cysteine protease activity.

All other arguments presented in the instant filing, regarding the rejection of Claims Claims 1-4 and 17-21 under 35 U.S.C. 101/112, have been addressed in prior Actions from the Office.

For these reasons and those explained in the prior actions, rejection of Claims 1-4 and 17-21 under 35 U.S.C. 101/112 because the claimed invention lacks patentable utility, is maintained.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Rejection of Claims 1-4 and 17-21 under 35 U.S.C. 112, first paragraph/enablement, for the reasons explained in the prior action, is maintained.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments. Polynucleotides encoding a polypeptide with at least 70% or 85%

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homology to SEQ ID NO: 2 are enabled by the instant specification. Procedures and methods for identifying variant polynucleotides that retain the activity of the parental nucleotide are commonly practiced by a skilled artisan. One of skill in the art can readily identify the region of the polynucleotide that encodes for the catalytic active site of SEQ ID NO: 2. Such knowledge allows a skilled artisan to modify a parental nucleic acid without undue experimentation while retaining its catalytic activity characteristic of a cysteine protease. Screening the resulting variants for the desired activity would not be undue experimentation.

These arguments are essentially the same as the arguments provided in Applicants' response of June 3, 2009. They are not found to be persuasive for the reasons set forth in the Action of July 6, 2009.

For these reasons and those explained in the prior action, rejection of Claims 1-4 and 17-21 under 35 U.S.C. 112, first paragraph/enablement, is maintained.

Written Description

Rejection of Claims 1-4 and 17-21 under 35 U.S.C. 112, first paragraph/written description, for the reasons explained in the prior action, is maintained.

In support of their request that said rejection be withdrawn, Applicants provide the following arguments. The feature of having a cysteine protease active site correlates the structure of the claimed polypeptides with their function as a cysteine protease. Notably, the claimed sequences are drawn to polynucleotides encoding a polypeptide with cysteine protease activity. As such, the potential genus is not as large as asserted by the Examiner.

This argument is not found to be persuasive because the specification fails to teach that the polynucleotide of SEQ ID NO: 1, or any variant thereof, encodes a protein having the recited

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activity. The specification also fails to teach the active site of the protein of SEQ ID NO: 2.

The skilled artisan would not recognize that Applicants were in possession of the genus of all proteins having at least 70% or 80% identity with SEQ ID NO: 2 and having cysteine protease activity.

For these reasons and those explained in the prior action, rejection of Claims 1-4 and 17-21 under 35 U.S.C. 112, first paragraph/written description, is maintained.

Allowable Subject Matter

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages. It is also requested that the serial number of the application and date of amendment be referenced on every page of the response.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/

Primary Examiner, Art Unit 1652